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**U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE**

**INFORMATION DISCLOSURE  
STATEMENT**

Docket Number:  
**01662/62005**

Application Number  
**10/799,376**

Filing Date  
**March 12, 2004**

Examiner  
**Patricia L. Morris**

Art Unit  
**1625**

Invention Title  
**CRYSTALLINE AND AMORPHOUS SOLIDS OF  
PANTOPRAZOLE AND PROCESSES FOR THEIR  
PREPARATION**

Inventors  
**FINKELSTEIN, et al.**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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Date: May 31, 2007

Signature: *Theresa Brown*

Sir:

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). The paragraphs marked below are applicable. It is believed that no fees other than those indicated below are due, but authorization is hereby given to charge any additional fees due, or to credit any overpayment, to **Kenyon & Kenyon LLP, deposit account 11-0600**.

☐ 1. This Information Disclosure Statement is being filed (a) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. §1.53(d), (b) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, (c) before the mailing date of a first Office Action on the merits in the present application, OR (d) before the mailing of a first office action after filing of a request for continued examination. No certification or fee is required.

☒ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a final action, Notice of Allowance, or any action that otherwise closes prosecution.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

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- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).
- ☒ c. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 CFR §1.97(c)(2).
- ☐ 3. This Information Disclosure Statement is being filed after the mailing date of a final action, Notice of Allowance or an action that otherwise closes prosecution, but before payment of the Issue Fee. Applicant(s) hereby request(s) that the Information Disclosure Statement be considered. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the petition fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in any counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).
- ☐ 4. Relevance of the non-English language reference(s) is discussed in the present specification.
- ☐ 5. The references were cited in office actions in counterpart foreign applications. English language version of the foreign corresponding foreign office actions and responses thereto are attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language reference(s) appears in the Appendix attached hereto.
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination of the present application.
- ☐ 8. This application is one of a series of related applications, identified in the attached Appendix, which are directed to related technical subject matter. The identification of those U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is

respectfully requested to consider the cited applications and the art cited therein during the examination.

☐ 9. The reference(s) was/were cited by or submitted to the Office in parent application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 CFR §1.98(d).

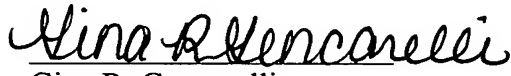
☐ 10. English-language Abstracts of the non-English language references are attached hereto.

☒ 11. Since this application was filed after June 30, 2003, copies of U.S. references are not included.

☐ 12. Other. The references cited herein were cited in an International Search Report of \_\_\_\_\_ provided herewith.

Respectfully submitted,

Date: May 31, 2007

  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	10/799,376
Filing Date	March 12, 2004
First Named Inventor	FINKELSTEIN et al.
Art Unit	1625
Examiner Name	Patricia L. Morris
Attorney Docket Number	01662/62005

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		4,508,905	04-02-1985	Schwartz et al.	
		4,555,318 (equivalent to EP 0 134 400)	11-26-1985	Rainer et al.	
		4,628,098	12-09-1986	Nohara et al.	
		5,045,552	09-03-1991	Souda et al.	
		5,708,013	01-13-1998	Shimomura et al.	
		5,391,752	02-21-1995	Hoerner et al.	
		6,017,560	01-25-2000	Hirai et al.	
		6,313,303	11-06-2001	Tagami et al.	
		6,423,846	07-23-2002	Moon et al.	
		2004/0138466	07-2004	Avrutov et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		EP 0 134 400	03-20-1985	Byk Gulden Lomborg Chem.		AB
		EP 302,720	02-08-1989	Takeda Chem. Indus. Ltd.		
		EP 484,265 A	05-06-1992	Palomo et al.		
		EP 0 533 264	03-24-1993	Merck & Co. Inc.		
		EP 1 270 555	01-02-2003	Esteve Quimica SA		
		ES 860 2765 (539,793)	03-16-1986	Farmhispania SA		AB
		ES 860 4929 (540,147)	08-01-1986	Tamarang, SA		AB
		ES 870 3868 (550,070)	05-16-1987	Labs. Hubber SA		AB
		GB 2 134 523	08-15-1984	Haessle AB		
		WO 99/47514	09-23-1999	Knoll Aktiengesellschaft		
		WO 03/062223	07-31-2003	Ulkar		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet 2 of 2

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Art Unit	1625
Examiner Name	Patricia L. Morris
Attorney Docket Number	01662/62005

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		A. Badwan et al. "Pantoprazole Sodium" in ANALYTICAL PROFILES OF DRUGS SUBSTANCES AND EXCIPIENTS (Brittain H G, Ed., Academic Press, Amsterdam), Vol 29, pp. 213-259 (2002) (p. 225, ¶ 3.4 and Table 1).	
		Drabowicz et al., "Synthesis of Sulphoxides; in Rappoport et al. THE CHEMISTRY OF SULPHONES AND SULPHOXIDES. p. 249 (J. Wiley & Sons: New York 1988).	
		Gamer A et al, "Pantoprazole: A New and More Specific Proton Pump Inhibitor", <i>Expert Opinion on Investigational Drugs</i> , 6 (7): 885-893 (1997).	
		Graul A et al, "Esomeprazole Magnesium(-)-Omeprazole Magnesium Perprazole (formerly) (S)-Omeprazole Magnesium H-199/18 Nexium", <i>Drugs of the Future</i> , 24 (11): 1178-1183 (1999).	
		Kotar-Jordan, B. "Solid State Characterization of New Pantoprazole Sodium Hydrate Forms" <i>Farm. Vestn.</i> , 54 (2): 411-412 (2003).	
		Moustafa, "Spectrophotometric Methods for the Determination of Lansoprazole and Pantoprazole Sodiumsesquihydrate.," <i>J. of Pharm. and Biomed. Analysis</i> , 22: 45-58 (2000).	
		Vyas K et al. "Lansoprazole, An Antiulcerative Drug", <i>Acta Crystallographica Section C. Crystal Structure Communications</i> , C56 (12): E572-E573 (2000).	
		Williams M P, et al., "Review Article: The Pharmacology of Rabeprazole," <i>Alimentary Pharmacology &amp; Therapeutics</i> , 13 (Suppl. 3): 3-10 (1999).	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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